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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,472	01/28/2002	Eric F. Bernstein	BERN-0045	2557
27723	7590	11/07/2003	EXAMINER	
PATRICK R. SCANLON PIERCE ATWOOD ONE MONUMENT SQUARE PORTLAND, ME 04101			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/913,472	<b>Applicant(s)</b> BERNSTEIN, ERIC F.	
	<b>Examiner</b> Scott D. Priebe	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5 is/are rejected.
- 7) ☒ Claim(s) 4 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed 8/28/03 has been entered. Claims 1-2 have been amended. Claims 3-6 have been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 102***

Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernstein et al., US 5,648,061, as evidenced by applicant's admission of prior art in the specification and Bernstein, E., US 5,840,734, for the reasons of record set forth in the Office action of 3/5/03.

Claims 1 and 2 have been amended to require that the reactive oxygen species are generated at sufficient levels for upregulating the elastin promoter. As disclosed in the '734 patent (col. 4, lines 38-59), a free radical scavenging compound, Tempol, inhibited expression of the CAT reporter under control of a human elastin promoter in transgenic mouse fibroblasts exposed to UVB. Tempol also absorbs UVB, and reduces the dose of UVB received by the fibroblasts. There is no evidence of record that Tempol has any direct on repair of DNA damage. Consequently, one concludes that free radical compounds (e.g. reactive oxygen species) generated by UVB exposure are at least partly responsible for induction of the elastin promoter.

Claims 1 and 2 remain rejected and new claims 3 and 5 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bernstein et al., US 6,018,098 as evidenced by applicant's

admission of prior art in the specification and Bernstein, E., US 5,840,734, for the reasons of record set forth in the Office action of 3/5/03 and the additional reasons set forth below.

Claims 1 and 2 have been amended to require that the reactive oxygen species are generated at sufficient levels for upregulating the elastin promoter. Claims 3 and 5 require that a chemical means be used for generating the reactive oxygen species be a chemical means. As disclosed in the '734 patent (col. 4, lines 38-59; col. 5, lines 14-31), a free radical scavenging compound, Tempol, inhibited expression of the CAT reporter under control of a human elastin promoter in transgenic mouse fibroblasts exposed either to UVB or to UVA and 8-methoxypsoralen (8-MOP). Tempol absorbs UVB, but not UVA, and reduces the dose of UVB received by the fibroblasts. Exposure to either UVA or 8-MOP alone did not induce CAT expression. There is no evidence of record that Tempol has any direct on repair of DNA damage. Consequently, one concludes that free radical compounds (e.g. reactive oxygen species) generated by exposure to either UVB or to UVA and 8-MOP are at least partly responsible for induction of the elastin promoter. With respect to claims 3 and 5, exposure to 8-MOP, a chemical, was required to produce the reactive oxygen species necessary for induction of the elastin promoter, i.e. a chemical means was used.

Claims 1-2 remain rejected and claims 3 and 5 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter for the reasons of record set forth in the Office action of 3/5/03.

Claims 1 and 2 remain rejected and claims 3 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bernstein et al., WO 96/37237, as evidenced by applicant's admission of prior art in the specification and Bernstein, E., US 5,840,734, for the reasons of record set forth in the Office action of 3/5/03 and the additional reasons set forth below.

Claims 1 and 2 have been amended to require that the reactive oxygen species are generated at sufficient levels for upregulating the elastin promoter. Claims 3 and 5 require that a chemical means be used for generating the reactive oxygen species be a chemical means. As disclosed in the '734 patent (col. 4, lines 38-59; col. 5, lines 14-31), a free radical scavenging compound, Tempol, inhibited expression of the CAT reporter under control of a human elastin promoter in transgenic mouse fibroblasts exposed either to UVB or to UVA and 8-methoxypsoralen (8-MOP). Tempol absorbs UVB, but not UVA, and reduces the dose of UVB received by the fibroblasts. Exposure to either UVA or 8-MOP alone did not induce CAT expression. There is no evidence of record that Tempol has any direct on repair of DNA damage. Consequently, one concludes that free radical compounds (e.g. reactive oxygen species) generated by exposure to either UVB or to UVA and 8-MOP are at least partly responsible for induction of the elastin promoter. With respect to claims 3 and 5, exposure to 8-MOP, a chemical, was required to produce the reactive oxygen species necessary for induction of the elastin promoter, i.e. a chemical means was used.

### ***Double Patenting***

Claims 1 and 2 remain and claims 3 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of each of U.S.

Patent Nos. 5,648,061 and 6,018,098 for the reasons of record set forth in the Office action of 3/5/03, and the new reasons indicated above with respect to the rejections under 35 USC 102(e).

***Response to Arguments***

Applicant's arguments filed 8/28/03 have been fully considered but they are not persuasive. Applicant asserts that radiation effects of UVB exposure primarily result from DNA damage, and that effects of UVA exposure primarily result from oxidative damage. No evidence has been made of record with respect to UVB, and the assertion is contradicted by the summary of prior art in the instant specification. Furthermore, US 5,840,734 discloses evidence that the induction of the elastin promoter in the assays of the '061 and '098 patents were due at least in part to reactive oxygen species generated by exposure to UVB or to UVA and 8-MOP, as discussed above. Also, there is no evidence of record that the elastin promoter is induced by DNA damage caused by UVB exposure, as opposed to reactive oxygen species produced by UVB or the combination of UVA and 8-MOP.

***Allowable Subject Matter***

Claims 4 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Kawaguchi et al. (Free Rad. Biol. Med. 23 (1): 162-165, 1997) discloses measuring elastin expression in cultured human dermal fibroblasts in response to reactive oxygen species generated by the xanthine/xanthine oxidase system as part of a study to elucidate the potential causes for elastin deposition in photoaging. While one of ordinary skill in the art in viewing this

art in combination with any of US 5,648,061, US 6,018,098, or WO 96/37237, would have concluded that it was feasible to replace induction of the elastin promoter by exposure to UVB or to UVA plus 8-MOP with the xanthine/xanthine oxidase system, there is no suggestion in the art of record that such a change would be desirable or have any particular advantage over assays using the induction systems using UV. The Federal Circuit has held that feasibility alone is not sufficient to establish obviousness, *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580 (Fed. Cir. 2000). Consequently, claims 4 and 6 are not obvious over the combination of one of the three patents and Kawaguchi.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

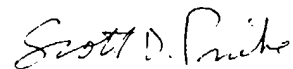
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe  
Primary Examiner  
Art Unit 1632